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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,821	09/01/1999	MICHAEL J. WARING	CV0244	5635

7590

05/28/2003

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/28/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/341,821

Applicant(s)

Waring et al.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 5, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, 13-15, and 17-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 13-15, and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25 6) ☐ Other:

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DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration and supplemental IDS, both filed 03/05/2003.

Claims 1-6, 8-10, 13-15, 17-20 are pending in the application.

1. The standing rejections:

(A) Claims 1-6, 8, 10, 13, 14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 560 014 ('014) in view of EP 666 081 ('081).

EP '014 discloses a spray apparatus includes a vessel with a dispensing means which can be a valve and nozzle mechanism or collapsible vessel with tube, or aerosol propellant and it contains a composition which can be administered to the skin, mucous membrane of the mouth and the nose (sinuses), tissue injury (wound), or body cavity (sinuses). The composition contains polyethylene glycol, propylene glycol and water (wound gel disclosed by the applicants). See the abstract; col.5, lines 4-6; col.14, lines 24-35; col.17, lines 25-27; col.22, line 52; col.23, line 8.

The reference does not teach the same composition as disclosed by applicant.

EP '081 teaches gel wound dressing comprising material comprising :

a) from about 0.05% to 10% by weight of natural gelling agent;

b) from about 1.0% to 10% by weight of hydrocolloid;

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c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

The wound dressing is packaged and sterilized. The gel composition of the reference can be extruded in the form of gel through a nozzle. See page 2, lines 20-24; page 3, lines 14-18. The gel of the reference has viscosity of 50-800 Pas.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the composition of EP '014 in the aerosol vessel that used to treat sinus wound by the composition disclosed by EP '081, motivated by the teaching of EP '081 that the gel composition has a viscosity that reduces the flow of the gel from the wound site and it can be extruded from a nozzle, with reasonable expectation of success of the derived gel from an aerosol as a wound dressing.

(B) Claims 9, 15, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '014 in view of EP '081 as applied to claims 1-6, 8, 10, 13, 14, and 20 above, and further in view of US 5,059,187.

EP '014 and EP '081 in combination do not teach a method of making the aerosol vessel.

US '187 teaches a method for providing an aerosol container and method for cleaning the wound including introducing the wound cleaning solution through an opening into a pouch and then the opening is closed by a valve, the container is then

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sterilized and the propellant is introduced into the can. See the abstract; col.3, lines 1-10; col.5, lines 8-21.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to include the gel for treating wound as disclosed by EP '014 in view of EP '081 in the aerosol vessel of US '187, motivated by the teaching of US '187 that the rigid container of the aerosol is adapted to withstand a high pressure (col.2, lines 18-21), with reasonable expectation of success of treating wounds by delivering gel composition from an aerosol vessel.

2. *Response to Arguments*

Applicant's arguments filed 03/05/2003 have been fully considered but they are not persuasive.

- EP '014 disclosed a vessel contains a liquid and not a gel. The device of the reference is not self sealed.
- EP '081 teaches a gel wound dressing but does not disclose the vessel that safely hold and dispense multiple doses of the gel.
- There is no reason other than the hindsight to substitute the composition of EP '081 for the composition of EP '014.
- Sperry does not teach the multiple doses, and does not teach the gel-form within the container.

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3. Examiner's position:

- The composition disclosed by EP '014 to be dispensed by the vessel contains water and polyethylene glycol and propylene glycol, as disclosed by applicant, and the composition coagulate after application and diffusion of the solvent, not liquid. No criticality has been shown in the gel form. EP '014 relied upon for teaching a wound dressing that is dispensed or sprayed from a vessel. Ep '014 is relied upon in combination with Ep '081, and one can not show nonobviousness by attacking the references individually when the rejection is based on combination. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., self-sealing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- As applicants themselves admitted, EP '081 disclosed a gel wound dressing comprising the same composition as the claimed composition. The difference between EP '081 and the present invention is the form of the container of the gel. EP '081 disclosed the gel is extruded through a nozzle, and this suggests the container of the gel to have a nozzle, and subsequently suggests the vessel of

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aerosol or tube. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the composition of EP '014 in the aerosol vessel that used to treat sinus wound by the composition disclosed by EP '081, motivated by the teaching of EP '081 that the gel composition has a viscosity that reduces the flow of the gel from the wound site and it can be extruded from a nozzle, with reasonable expectation of success of the derived gel from an aerosol as a wound dressing. No superior and unexpected results of record showing the criticality of the multiple doses in the container, and both references are silent regarding the plurality of doses.

- In response to applicant's argument that the examiner's conclusion of obviousness is based upon the hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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- Sperry is relied upon for teaching the method of making the aerosol vessel. It is relied upon in combination with other references, EP '014 and EP '081, and one can not show nonobviousness by attacking the references individually when the rejection is based on combination. No superior and unexpected results of record showing the criticality of the multiple doses in the container, and the reference is silent regarding the plurality of doses. Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to include the gel for treating wound as disclosed by EP '014 in view of EP '081 in the aerosol vessel of US '187, motivated by the teaching of US '187 that the rigid container of the aerosol is adapted to withstand a high pressure (col.2, lines 18-21), with reasonable expectation of success of treating wounds by delivering gel composition from an aerosol vessel.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

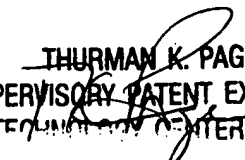
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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